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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,378	07/14/2003	Steven Walkley	2543-I-022PCT/CIP	5426
23565	7590	05/15/2006		EXAMINER
KLAUBER & JACKSON				SULLIVAN, DANIEL M
411 HACKENSACK AVENUE			ART UNIT	PAPER NUMBER
HACKENSACK, NJ 07601				1636

DATE MAILED: 05/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/619,378	WALKLEY, STEVEN	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 February 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 21,22,25,26,28,29,32,33,36 and 37 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 21,22,25,26,28,29,32,33,36 and 37 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/15/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

This Office Action is a reply to the Paper filed 15 February 2006 in response to the Non-Final Office Action mailed 11 October 2005. Claims 21-25 were considered in the 11 October Office Action. Claims 23, 24, 27, 30, 31, 34 and 35 were canceled, claims 21, 25, 28 and 32 were amended and claims 36 and 37 were added in the 15 February Paper. Claims 21, 22, 25, 26, 28, 29, 32, 33, 36 and 37 are pending and under consideration.

Priority

Correction of the priority claim under 35 USC §119 and 120 by deletion of reference to applications 10/042,527, PCT/GB00/01560 and UK 9909066.4 from the first line of the specification is acknowledged.

Regarding the 0100889.5 application, receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. It is noted that the assignee named in the 0100889.5 filing is the same as the assignee named in the instant case, which is sufficient under 35 USC §119(a).

Response to Amendment and Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21, 22, 28 and 29 stand rejected and newly added claims 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons set forth in the 11 October Office Action (pp. 3-7) and herein below in the response to Applicant arguments.

Response to Arguments

In response to the *prima facie* rejection of record, Applicant has amended the claims such that they now recite that the inhibitor of glucosylceramide synthesis administered is an imino sugar. In the remarks (p. 6, ¶ 2), Applicant states, “In that the claims are amended herein to recite that the inhibitor of glucosylceramide synthesis is an imino sugar, for which the Examiner acknowledges the specification presents detailed written description, Applicant believes that the rejection is nullified”. However, as applicant acknowledges in the sentence immediately preceding the statement quoted herein, the Examiner has actually affirmed only that the specification provides detailed description and reduction to practice of imino sugar compounds capable of inhibiting glucosylceramide synthase.

As stated in the 11 October Office Action (p. 6, ¶ 1; emphasis added), “The specification does not describe small molecule inhibitors of enzymes involved in synthesis of glucosylceramide synthesis [sic] other than glucosylceramide synthase inhibitors...” Thus, contrary to Applicant’s assertion, the Office Action does not acknowledge that the specification provides adequate descriptive support for any imino sugar inhibitor of glucosylceramide synthesis other than inhibitors of the glucosylceramide synthase enzyme.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Therefore, the claims stand rejected under 35 USC §112, first paragraph, as lacking adequate descriptive support.

Claims 21, 22, 25, 26, 28, 29, 32 and 33 stand rejected and newly added claims 36 and 37 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising administering an imino sugar inhibitor of glucosylceramide synthase in an amount sufficient to provide the symptomatic relief recited in the claims (*i.e.*, slowing of mucopolysaccharide disease progression, reduction of neuronal glycolipid storage, reduction of pathological features resulting from glycolipid accumulation or improving survival), does not reasonably provide enablement for a method comprising administering a "therapeutically effective amount" of an inhibitor of glucosylceramide synthesis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained to the extent recited above for the reasons set forth in the 11 October Office Action (pp. 7-17). As clearly stated therein, "the instant specification defines 'treatment' as 'the administration of medicine or the performance of medical procedures with respect to a patient, for either prophylaxis (prevention) or to cure the infirmity or malady in the instance where the patient is afflicted' and paragraph 52 defines 'therapeutically effective amount' as 'an amount of a reagent sufficient to achieve the desired treatment effect.' Thus, construed in light of the specification, the claims are directed to methods of preventing or curing mucopolysaccharidosis or methods comprising administering an amount of an agent in an

amount sufficient to obtain prevention or cure in a patient having mucopolysaccharide disease” (p. 8, ¶ 3; emphasis added). In view of Applicant’s arguments in the 15 February Paper and the teaching at paragraph 137 of the instant specification, which states, “NB-DNJ markedly reduces the pathological features in the model of MPSIIIA”, which is understood to mean that each of the pathological features listed in paragraph 131 were found to be improved upon treatment with NB-DNJ, the specification is considered enabling for providing symptomatic relief. However, for the reasons provided in the previous Office Action, the specification is not enabling for a method that requires administration of an amount of an inhibitor of glucosylceramide synthase sufficient to achieve a “treatment effect” as treatment is defined in the specification to mean prevention or cure. Therefore, for reasons of record, the disclosure is not enabling for the subject matter claimed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (<http://pair-direct.uspto.gov>) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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Primary Examiner
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DANIEL M. SULLIVAN
PATENT EXAMINER